REMARKS

Pending claims

In the interest of simplifying and expediting prosecution, Applicants have replaced the existing claim set with new Claims 22-42. This amendment does not introduce any new matter.

Restriction Requirement

In the Restriction Requirement, the Examiner requested Applicants to elect one of the following inventions. The Examiner subdivided the claimed subject matter into numbered "Sets" which were further subdivided by SEQ ID NO into numbered "Inventions."

Set 1:

Invention 1 (Claims 1-7) drawn to polynucleotide encoding DAPK-1 (SEQ ID NO:1);

Invention 2 (Claims 1-7) drawn to polynucleotide encoding DAPK-2 (SEQ ID NO:2);

Invention 3 (Claims 1-7) drawn to polynucleotide encoding DAPK-4 (SEQ ID NO:4);

Invention 4 (Claims 1-7) drawn to polynucleotide encoding DAPK-5 (SEQ ID NO:5);

Invention 5 (Claims 1-7) drawn to polynucleotide encoding DAPK-6 (SEQ ID NO:6); and

Invention 6 (Claims 1-7) drawn to polynucleotide encoding DAPK-7 (SEQ ID NO:7).

Set 2:

Invention 7 (Claims 8-10) drawn to a method for detecting polynucleotides via polynucleotide encoding DAPK-1 (SEQ ID NO:1);

Invention 8 (Claims 8-10) drawn to a method for detecting polynucleotides via polynucleotide encoding DAPK-2 (SEQ ID NO:2);

Invention 9 (Claims 8-10) drawn to a method for detecting polynucleotides via polynucleotide encoding DAPK-4 (SEQ ID NO:4);

Invention 10 (Claims 8-10) drawn to a method for detecting polynucleotides via polynucleotide encoding DAPK-5 (SEQ ID NO:5);

Invention 11 (Claims 8-10) drawn to a method for detecting polynucleotides via polynucleotide encoding DAPK-6 (SEQ ID NO:6); and

Invention 12 (Claims 8-10) drawn to a method for detecting polynucleotides via polynucleotide encoding DAPK-7 (SEQ ID NO:7).

Set 3:

Invention 13 (Claims 11 and 12) drawn to a method for detecting molecules that bind to polynucleotides encoding DAPK-1 (SEQ ID NO:1);

Invention 14 (Claims 11 and 12) drawn to a method for detecting molecules that bind to polynucleotides encoding DAPK-2 (SEQ ID NO:2);

Invention 15 (Claims 11 and 12) drawn to a method for detecting molecules that bind to polynucleotides encoding DAPK-4 (SEQ ID NO:4);

Invention 16 (Claims 11 and 12) drawn to a method for detecting molecules that bind to polynucleotides encoding DAPK-5 (SEQ ID NO:5);

Invention 17 (Claims 11 and 12) drawn to a method for detecting molecules that bind to polynucleotides encoding DAPK-6 (SEQ ID NO:6); and

Invention 18 (Claims 11 and 12) drawn to a method for detecting molecules that bind to polynucleotides encoding DAPK-7 (SEQ ID NO:7).

Set 4:

Invention 19 (Claim 13) drawn to DAPK-1 (SEQ ID NO:1);

Invention 20 (Claim 13) drawn to DAPK-2 (SEQ ID NO:2);

Invention 21 (Claim 13) drawn to DAPK-4 (SEQ ID NO:4);

Invention 22 (Claim 13) drawn to DAPK-5 (SEQ ID NO:5);

Invention 23 (Claim 13) drawn to DAPK-6 (SEQ ID NO:6); and

Invention 24 (Claim 13) drawn to DAPK-7 (SEQ ID NO:7).

Set 5:

Invention 25 (Claims 14-16 and 18) drawn to antibody against DAPK-1 (SEQ ID NO:1);

Invention 26 (Claims 14-16 and 18) drawn to antibody against DAPK-2 (SEQ ID NO:2);

Invention 27 (Claims 14-16 and 18) drawn to antibody against DAPK-4 (SEQ ID NO:4);

Invention 28 (Claims 14-16 and 18) drawn to antibody against DAPK-5 (SEQ ID NO:5);

Invention 29 (Claims 14-16 and 18) drawn to antibody against DAPK-6 (SEQ ID NO:6); and

Invention 30 (Claims 14-16 and 18) drawn to antibody against DAPK-7 (SEQ ID NO:7).

Set 6:

Invention 31 (Claims 17 and 19) drawn to a method of diagnosing disease via the antibody against DAPK-1 (SEQ ID NO:1);

Invention 32 (Claims 17 and 19) drawn to a method of diagnosing disease via the antibody against DAPK-2 (SEQ ID NO:2);

Invention 33 (Claims 17 and 19) drawn to a method of diagnosing disease via the antibody against DAPK-4 (SEQ ID NO:4);

Invention 34 (Claims 17 and 19) drawn to a method of diagnosing disease via the antibody against DAPK-5 (SEQ ID NO:5);

Invention 35 (Claims 17 and 19) drawn to a method of diagnosing disease via the antibody against DAPK-6 (SEQ ID NO:6); and

Invention 36 (Claims 17 and 19) drawn to a method of diagnosing disease via the antibody against DAPK-7 (SEQ ID NO:7).

Set 7:

Invention 37 (Claims 20 and 21) drawn to a method of detecting/purifying a DAPK via the antibody against DAPK-1 (SEQ ID NO:1);

Invention 38 (Claims 20 and 21) drawn to a method of detecting/purifying a DAPK via the antibody against DAPK-2 (SEQ ID NO:2);

Invention 39 (Claims 20 and 21) drawn to a method of detecting/purifying a DAPK via the antibody against DAPK-4 (SEQ ID NO:4);

Invention 40 (Claims 20 and 21) drawn to a method of detecting/purifying a DAPK via the antibody against DAPK-5 (SEQ ID NO:5);

Invention 41 (Claims 20 and 21) drawn to a method of detecting/purifying a DAPK via the antibody against DAPK-6 (SEQ ID NO:6); and

Invention 42 (Claims 20 and 21) drawn to a method of detecting/purifying a DAPK via the antibody against DAPK-7 (SEQ ID NO:7).

Applicants have canceled the entire claim set in favor of newly presented claims which are submitted to more clearly define Applicants' invention. For the Examiner's convenience, the correspondence between claims in the original claim set and in the amended claim set is noted below:

Sets	Old Claims	New Claims	Subject Matter
1	1-7	24-32	Polynucleotides, vectors, cells, and methods of use
2	8-10	33-35	Method of detecting a polynucleotide
3	11 and 12	—	Method for detecting molecules that bind a polynucleotide
4	13	22-23	Polypeptides
5	14-16 and 18	—	Antibodies
6	17 and 19	—	Methods of diagnosing disease using antibodies
7	20 and 21	—	Methods of detecting/purifying a polypeptide using an antibody
—	—	36 and 37	Methods of using polynucleotides
—	—	38-42	Microarrays and methods of use

Applicants hereby elect, with traverse, to prosecute the claims of Set 1, which includes and is drawn to Claims 24-32, corresponding to Claims 1-7, now canceled. Applicants also traverse the restriction requirement to elect a particular SEQ ID NO:. Applicants provisionally elect the portion of Claims 24-32 (Set 1) directed to SEQ ID NO:2 (Invention 2), also with traverse.

Applicants submit that the invention encompassed by newly added Claims 38, 40, 41, and 42, drawn to microarrays, could be examined at the same time as the invention encompassed by the claims of Set 1 (Claims 24-32) without undue burden on the Examiner. For example, a search of the prior art to determine the novelty of the polynucleotides of Set 1 would provide information regarding the novelty of the microarrays of Claims 38, 40, 41, and 42.

In addition, Applicants also traverse this restriction requirement insofar as it is, in effect, a requirement for election of species as between elements in Markush groups (those elements being, respectively, SEQ ID NO:8-14 with respect to the polynucleotides and SEQ ID NO:1-7 with respect to the polypeptides encoded by the polynucleotides. The Examiner's attention is directed to the Patent Office's own requirements for Markush practice, set forth in the 8th edition of the M.P.E.P. (August 2001) at § 803.02 regarding restriction requirements in Markush-type claims:

> PRACTICE RE MARKUSH-TYPE CLAIMS
>
> If the members of the Markush group are **sufficiently few in number or so closely related** that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction.
>
> Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas,* 580 F.2d 461, 198 USPQ 334 (CCPA 1978), **it is improper for the Office to refuse to examine that which applicants regard as their invention**, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d

1059 (Bd. Pat. App. & Int. 1984). Broadly, **unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.**

This subsection deals with Markush-type generic claims which include a plurality of alternatively usable substances or members. In most cases, a recitation by enumeration is used because there is no appropriate or true generic language. A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, **the examiner may require a provisional election of a single species** prior to examination on the merits. The provisional election will be given effect in the event that the Markush-type claim should be found not allowable. Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable over the prior art, examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

As an example, in the case of an application with a Markush-type claim drawn to the compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D, and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD, or CE. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the nonelected species would be held withdrawn from further consideration. As in the prevailing practice, a second action on the rejected claims would be made final.

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a *non-elected species,* the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the

claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry. [emphasis added]

As can be seen from the above, it is clear that the present Restriction Requirement does not meet the Patent Office's own requirements.

The Examiner alleged that "[i]nventions 1-6 are drawn to polynucleotides encoding diseases associated kinases having different structures. Therefore, each DAPK is patentably distinct one from the other. If any one of Inventions 1-6 is elected, the examination of the claims will be carried out only in-so-far as the claimed are drawn to the elected subject matter." (Office Action, page 2.)

However, is noted that if the number of "members of the Markush group are **sufficiently few in number or so closely related** that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to **independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction.**" Withdrawal of the restriction requirement, at least as between a reasonable number of the specific sequences each in the claims is required on that basis alone.

Moreover, Applicants submit that examination of all seven sequences (polynucleotides encoding SEQ ID NO:1-7; polynucleotides of SEQ ID NO:8-14) in the instant application would not be an undue burden on the Examiner. In the previous application to which the instant case claims priority (U.S. patent application Serial No. 09/272,796 filed on March 19, 1999, now U.S. Patent 6,207,148), claims to the polypeptides of SEQ ID NO:1-7 were examined together. The apparent lack of burden on the Examiner in U.S. patent application Serial No. 09/272,796, as well as the availability to the instant Examiner of the results of the searches already made in the parent applications U.S. patent application Serial No. 09/272,796 and U.S. patent application Serial No. 08/878,989, suggest that there would be no undue burden on instant Examiner to examine claims to the polynucleotides encoding SEQ ID NO:1-7 and the polynucleotides of SEQ ID NO:8-14 in the present application.

Furthermore, **it is improper for the Office to refuse to examine that which applicants regard as their invention**, unless the subject matter in a claim lacks unity of invention. The

polynucleotides of the present invention, share a common utility in, for example, toxicology studies based on expression profiling.

In addition, Applicants respectfully submit that the seven polynucleotides encoding SEQ ID NO:1-7, and the seven polynucleotides of SEQ ID NO:8-14, share common utility as they share homology to polynucleotides encoding protein kinases. This homology, and the common utility derived from this homology, are disclosed in the Specification. Protein kinases are a well characterized class of enzymes that share multiple structural features that are essential to their common utility as disclosed in the specification e.g., at page 1, line 20 through page 2, line 13. In particular, as disclosed in the specification e.g., at page 17, line 24 through page 19, line 29, and in Figures 1-5, SEQ ID NO:1-5 share an ATP-binding motif, a substantial structure that is disclosed as being essential for their common utility. Hence the polynucleotides of the invention are indeed structurally related.

Furthermore, even if the claims could be considered to be "Markush-type generic claims which include a plurality of alternatively usable substances or members," it is further noted that the M.P.E.P states that "A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, **the examiner may require a provisional election of a single species** prior to examination on the merits." This clearly applies in the present case.

Finally, Examiner's attention is directed to the M.P.E.P. at § 803.04 (Restriction - Nucleotide Sequences, EXAMPLES OF NUCLEOTIDE SEQUENCE CLAIMS) which states:

> Applications claiming more than ten individual independent and distinct nucleotide sequences in alternative form, such as set forth in example (A), will be subject to a restriction requirement. Only the ten nucleotide sequences selected in response to the restriction requirement and any other claimed sequences which are patentably indistinct therefrom will be examined.
>
> Applications claiming only a combination of nucleotide sequences, such as set forth in example (B), will generally not be subject to a restriction requirement. The presence of one novel and nonobvious sequence within the combination will render the entire combination allowable. The combination will be searched until one nucleotide sequence is found to be allowable. The order of searching will be chosen by the

examiner to maximize the identification of an allowable sequence. If no individual nucleotide sequence is found to be allowable, the examiner will consider whether the combination of sequences taken as a whole renders the claim allowable.

The instant application claims seven polypeptide sequences (SEQ ID NO:1-7) and seven polynucleotide sequences (SEQ ID NO:8-14) and the claims examined clearly should not be limited by an election of only a single sequence under the guidelines set forth in the M.P.E.P. at § 803.04.

Therefore, it is respectfully submitted that, upon searching and examining SEQ ID NO:2 and finding no prior art over which SEQ ID NO:2 can be rejected, the Examiner must extend the search of the Markush-type claim to include the non-elected species.

Applicants further submit that newly added Claims 33-35, corresponding to original claims 8-10 of Set 2, now canceled, and newly added Claims 36, 37, and 39 are methods of using the polynucleotides of Set 1, which should be examined together with the polynucleotides of Set 1, per the Commissioner' s Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)" which sets forth the rules, upon allowance of product claims, for rejoinder of process claims covering the same scope of products.

Accordingly, because the search required to identify prior art relevant to the claims of Set 1 (Claims 24-32) and Set 2 (Claims 33-35), as well as Claims 36-42 would substantially overlap, Applicants respectfully submit that examination of Claims 24-42, with respect to polypeptides of SEQ ID NO:1-7 and polynucleotides of SEQ ID NO:8-14, would pose no undue burden. Thus, Applicants request reconsideration and withdrawal of the Restriction Requirement and examination of Claims 24-42, with respect to polypeptides of SEQ ID NO:1-7 and polynucleotides of SEQ ID NO:8-14. Applicants reserve the right to prosecute the subject matter of non-elected claims, or of any subject matter disclosed but not herein claimed, in a later continuation or divisional application.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 09-0108.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 1-21 have been canceled.

Claims 22-42 have been added.